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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,273	03/01/2004	John W. Hanrahan	MGU-0027	3977

EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

7590  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, NJ 08053

09/11/2007

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/790,273

Applicant(s)

HANRAHAN ET AL.

Examiner

Steven H. Standley

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**Detailed Action**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/05/2006 has been entered.

2. Claims 7-8 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

**Objections/Rejections:Withdrawn**

***Claim Rejections - 35 USC § 112***

Rejection of claims 7-8 under 35 USC § 112, 1<sup>st</sup> paragraph, enablement is withdrawn due to applicant's amendment.

**Objections/Rejections: Maintained/New Grounds**

***Claim Rejections - 35 USC § 103***

Rejection of claims 7-8 under 35 USC § 103(a) is maintained for the reasons made of record in the office action dated 8/08/06 and 1/29/07. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues first on page 6 of the Remarks dated 7/30/07 that the references do not teach the unexpected result that the biotin tag does not disrupt the misfolded state of the protein. Firstly,

Applicant is arguing limitations that are not in the claims. Secondly, the mutation that causes ER retention of CFTR F508 is known. It is Phenylalanine amino acid 508. The fact that a tag introduced elsewhere does not disrupt ER retention is not novel at all. The Examiner cannot find any examples, for instance, of introduction of a tag into CFTR that overcomes its ER retention. Lastly, one of ordinary skill in the art would expect to be able to put the tag pretty much anywhere in the extracellular aspect of the protein and have the invention work.

Applicant also argues that Heda et al only teach labeling only after the protein has reached the cell surface. This is true in the case of the surface measurements of protein made by Heda et al, but it is also true of applicant's invention. Applicant does not actually biotinylate the tag until the protein goes to the cell surface. Otherwise, Applicant could not distinguish between protein that was folded correctly and protein that wasn't.

Applicant also argues that Heda et al does not teach permeabilization because Heda teaches lysis with 1% SDS as apposed to lysis with triton X-100 or digitonin or saponin. This is not found persuasive because SDS like all the other 'permeabilizing agents' is a detergent. Detergents serve to disrupt the lipid bilayer surrounding cells. Thus, the purpose for use is exactly the same: to expose the intracellular milieu to probing for the protein.

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**Conclusion**

No claim is allowed.

**Advisory information**

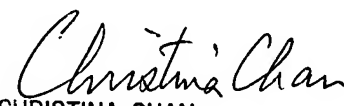
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on **(571) 272-0841**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.  
8/31/07



  
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